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UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

KIM SIZEMORE,

Plaintiff,

vs.

ZIMMER, INC.; ZIMMER HOLDINGS, INC.;
WILSON/PHILLIPS HOLDINGS, INC. a/k/a
ZIMMER WILSON PHILLIPS, AND ZIMMER
ORTHOPAEDIC SURGICAL PRODUCTS,
INC.,

Defendants.

Case No.:

COMPLAINT

JURY DEMAND

COMES NOW the Plaintiff, Kim Sizemore, by and through her undersigned Counsel,
and for her Complaint against the Defendants, alleges as follows:

NATURE OF THE CASE

1
2 1. This is an action for damages suffered by Kim Sizemore, as a direct and
3 proximate result of Defendants' wrongful conduct in connection with the development, design,
4 manufacture, distribution, and selling of Defendants' knee replacement product, the Zimmer
5 NexGen CR and the Zimmer NexGen CR-Flex Porous Femoral knee replacement system
6 (hereinafter "Zimmer NexGen Knee").

7 2. Defendants knew or should have known that the Zimmer NexGen Knee can
8 loosen in patients, such as Plaintiff Kim Sizemore, causing personal injury, significant pain, and
9 loss of movement, and that this injury can only be remedied through subsequent revision surgery
10 and/or hip replacement. Further, Defendants misled health care professionals and the public into
11 believing that the Zimmer NexGen Knee was safe and effective for use in knee replacement
12 surgery; engaged in deceptive, misleading and unconscionable promotional or sales methods to
13 convince health care professionals to utilize the Zimmer NexGen Knee, even though Defendants
14 knew or should have known that the Zimmer NexGen Knee was unreasonably unsafe; and failed
15 to warn health care professionals and the public about the safety risks of the Zimmer NexGen
16 Knee.

PARTIES

17
18 3. Plaintiff Kim Sizemore is a citizen of the State of Nevada, and a resident of Las
19 Vegas, Nevada.

20 4. Defendant Zimmer, Inc. is a corporation organized and existing under the laws of
21 Delaware, and has its principal place of business located in Warsaw, Indiana.

22 5. Defendant Zimmer Holdings, Inc. is a corporation organized and existing under
23 the laws of Delaware, and has its principal place of business located in Warsaw, Indiana.

24 6. Defendant Wilson/Phillips Holdings, Inc. a/k/a Zimmer Wilson Phillips is a
25 corporation organized and existing under the laws of Texas, and has its principal place of
26 business in Richardson, Texas.

27 7. Defendant Zimmer Orthopaedic Surgical Products, Inc. is a corporation organized
28 and existing under the laws of Ohio, and has its principal place of business in Dover, Ohio.

1 8. At all times material hereto, Defendants developed, designed, tested,
2 manufactured, distributed, marketed, and sold the Zimmer NexGen Knee. Defendants' products,
3 including the Zimmer NexGen Knee, are sold throughout the world, including within the state of
4 Nevada.

5 **JURISDICTION AND VENUE**

6 9. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiff and
7 Defendants are citizens of different States and the amount in controversy exceeds \$75,000
8 exclusive of interest and costs.

9 10. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. §
10 1391(a), as a substantial number of the events, actions or omissions giving rise to Plaintiff's
11 claims occurred in this district. At all times material hereto, Defendants conducted substantial
12 business in this district.

13 **FACTUAL BACKGROUND**

14 **KNEE REPLACEMENT BACKGROUND**

15 11. Total knee arthroplasty (TKA), also called total knee replacement, is a common
16 medical procedure performed. The surgery is designed to help relieve pain and improve joint
17 function in people with severe knee degeneration due to arthritis or trauma.

18 12. Upon information and belief, the TKA procedure is done by separating the
19 muscles and ligaments around the knee to expose the inside of the joint. The ends of the thigh
20 bone (femur) and the shin bone (tibia) are removed as is often the underside of the kneecap
21 (patella).

22 13. Upon information and belief, about 85 to 90 percent of total knee replacements
23 are successful up to ten years.

24 14. Mechanical loosening means that for some reason (other than infection) the
25 attachment between the artificial knee and the bone has become loose.

26 15. Upon information and belief, loosening of an artificial knee can be diagnosed
27 using X-ray. X-ray pictures of a loose knee joint there are one or more radiolucent lines around
28 the contours of the artificial knee joint.

1 16. A loose artificial knee is a problem because it causes pain and wearing away of
2 the bone. A painful loose knee can restrict the patient's daily activities severely. A loose
3 artificial knee also involves severe psychical burden for the patient.

4 17. Once the pain becomes unbearable or the individual loses function of the knee,
5 another operation will probably be required to revise the knee replacement. A loose, painful
6 artificial knee can usually, but not always, be replaced.

7 18. The purpose of knee revision surgery is to remove a failed knee implant and
8 replace it with a new one.

9 19. Upon information and belief, in a revision operation of a total knee failed by
10 loosening the biggest problem is usually to reconstruct the severe bone loss caused by bone
11 destruction around the failed total knee prosthesis, and restore the stability in the revised total
12 knee.

13 20. Upon information and belief, the results of a revision operation are not as good as
14 the first, and the risks of complications are higher. The range of motion in the knee after the
15 revision surgery may be smaller and the walking capacity may be also diminished. The rate of
16 loosening is higher after revision surgery than in primary knee replacement surgery.

17 **ZIMMER NEXGEN KNEE FACTS**

18 21. Zimmer was founded in 1927, and purports to be a worldwide leader in the design
19 and manufacture of orthopaedic reconstructive, spinal and trauma devices, dental implants, and
20 related orthopaedic surgical products.

21 22. The Zimmer NexGen Knee uses this alloy component to attach the bottom of the
22 thigh bone to the replacement knee without traditional cement to glue it in place.

23 23. The Zimmer NexGen Knee uses a "high-flex" porous femoral component made of
24 a porous fiber metal and a cobalt-chromium-molybdenum alloy. The cobalt-chromium-
25 molybdenum alloy on the surface that allows bone to grow into the mesh and relies on bone
26 growing into the surface of the implant for fixation.

27 24. The Zimmer NexGen Knee is not cemented in place during implantation, rather
28 the patient's bone is supposed to fuse to the implant. The cementless implant relies on the bone

1 naturally fusing with the implant. These implants have a surface topography that is conducive to
2 attracting new bone growth.

3 25. Defendants generally, manufactured, labeled, packaged, distributed, supplied,
4 marketed, advertised, and/or otherwise engaged in all activities that are part and parcel of the
5 sale and distribution of a pharmaceutical, and by said activities, caused the Zimmer NexGen
6 Knee to be placed into the stream of commerce throughout the United States.

7 26. Defendants made, participated in and/or contributed to filings with the FDA in
8 conjunction with the approval process for the Zimmer NexGen Knee.

9 27. Upon information and belief, Defendants was in control of the design, assembly,
10 manufacture, marketing, distribution, packaging, labeling, processing, supplying, promotion,
11 sales, and the issuance of product warnings and related information with respect to the Zimmer
12 NexGen Knee.

13 28. Defendants were at all times material hereto subject to the laws of the United
14 States of America, including provisions relating to the FDA, and the rules and regulations
15 thereof, in conjunction with the approval process, labeling, and other after-market activities that
16 pertain to the Zimmer NexGen Knee.

17 29. The Zimmer NexGen Knee has been widely advertised, marketed and represented
18 by the Defendants as a safe and effective treatment.

19 **ZIMMER NEXGEN KNEE PROBLEMS**

20 30. In 2010, Dr. Richard A. Berger, a Zimmer consultant, and her colleague Dr. Craig
21 J. Della Valle, presented a paper at a national meeting of the American Association of
22 Orthopedic Surgeons showing that approximately 9% percent of their patients who had the
23 Zimmer NexGen Knee implanted required revision surgery and 36% showed signs of the knee
24 implant loosening within one year of implant.

25 31. From the time that Defendants first began selling the Zimmer NexGen Knee in
26 the United States, the product labeling and product information for the Zimmer NexGen Knee
27 failed to contain adequate information, instructions, and warnings concerning implantation of the
28 product and the risks that the Zimmer NexGen Knee can loosen in patients.

32. Despite its knowledge of the serious injuries associated with use of the Zimmer NexGen Knee, Defendants engaged in a marketing and advertising program which as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of the Zimmer NexGen Knee was safe.

33. Upon information and belief, Defendants downplayed and understated the health hazards and risks associated with the use of the Zimmer NexGen Knee and through promotional literature as well as sales visits to orthopaedic surgeons, deceived doctors and potential users of the Zimmer NexGen Knee by relaying positive information, while concealing the nature and extent of known adverse and serious health effects.

FACTUAL ALLEGATIONS

34. Prior to June 22, 2009, the treating physician for Plaintiff, as well as Plaintiff, were exposed to the aforementioned advertising and marketing campaign directly by the Defendants.

35. Plaintiff Kim Sizemore and Plaintiff's physician, either through direct promotional contact with Sales Representative Defendants, through word-of-mouth from other health care providers, and/or through promotional materials, received the information the Defendants intended that they receive, to-wit: that the Zimmer NexGen Knee was safe and effective for use in TKA procedures.

36. On June 22, 2009, Plaintiff's physician implanted a Zimmer NexGen Knee.

37. Plaintiff began experiencing severe and debilitating pain 4 months after implant.

38. Plaintiff returned to Plaintiff's physician and was advised her Zimmer NexGen Knee was experiencing "loosening" and would need to be revised.

39. On October 14, 2010, Plaintiff had a second surgery to revise/replace her previously implanted Zimmer NexGen Knee.

40. As a direct and proximate result of the use of the Zimmer NexGen Knee, Plaintiff suffered, and continues to suffer, serious bodily injury and harm.

41. As a direct and proximate result of the use of the Zimmer NexGen Knee, Plaintiff incurred, and continues to incur, medical expenses to treat her injuries and condition.

42. At no time material to her use of the Zimmer NexGen Knee was Plaintiff or her physicians told, warned, or given information about the higher risks of loosening in the Zimmer NexGen Knee.

COUNT I

(Strict Liability)

43. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

44. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of Zimmer NexGen Knee. Defendants designed, manufactured, marketed, and sold Zimmer NexGen Knee to medical professionals and their patients, knowing it would be implanted for knee replacements.

45. Zimmer NexGen Knee as designed, manufactured, marketed and sold by Defendants reached Plaintiff without substantial change in its condition and was used by Plaintiff in a reasonably foreseeable and intended manner.

46. Zimmer NexGen Knee was “defective” and “unreasonably dangerous” when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that Zimmer NexGen Knee was in a condition not suitable for their proper and intended use among patients.

47. The Zimmer NexGen Knee was used in the manner for which it was intended, that is, for artificial knee replacement. This use resulted in injury to Plaintiff.

48. Plaintiff was not able to discover, nor could he have discovered through the exercise of reasonable care, the defective nature of the Zimmer NexGen Knee. Further, in no way could Plaintiff have known that Defendants had designed, developed, and manufactured the Zimmer NexGen Knee in such a way as to increase the risk of harm or injury to the recipients of it.

49. The Zimmer NexGen Knee is defective in design because of its propensity to loosen and cause patients unnecessary pain and repeat surgical procedures.

50. The Zimmer NexGen Knee is unreasonably dangerous because it was sold to Plaintiff without adequate warnings regarding, inter alia, the propensity of Zimmer NexGen Knee to loosen and cause serious pain and necessitate additional surgery; the post-marketing experience of higher rates of loosening and revision surgery with the Zimmer NexGen Knee; and the probability of suffering loosening and revision surgery.

51. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable at the time Defendants sold Zimmer NexGen Knee to Plaintiff.

52. Defendants had knowledge and information confirming the defective and dangerous nature of the Zimmer NexGen Knee. Despite this knowledge and information, Defendants failed to adequately and sufficiently warn Plaintiff and her physicians that Zimmer NexGen Knee causes serious injuries including, loosening and revision surgery.

53. As a direct and proximate result of Defendants' wrongful conduct, including Zimmer NexGen Knee's defective and dangerous design and inadequate warnings, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

54. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II

(Products Liability - Failure To Warn)

55. Plaintiff repeats and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

56. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of

1 commerce the Zimmer NexGen Knee and, in the course of same, directly advertised or marketed
2 the product to the FDA, health care professionals, and consumers, or persons responsible for
3 consumers, and therefore had a duty to warn of the risks associated with the use of the Zimmer
4 NexGen Knee.

5 57. Defendants failed to adequately warn health care professionals and the public,
6 including Plaintiff Kim Sizemore and her prescribing physician, of the true risks of the Zimmer
7 NexGen Knee, including that the Zimmer NexGen Knee could loosen, causing severe pain and
8 injury, and requiring further treatment, including revision surgery and/or knee replacement.

9 58. Defendants failed to timely and reasonably warn of material facts regarding the
10 safety and efficacy of the Zimmer NexGen Knee. Had they done so, proper warnings would
11 have been heeded and no health care professional, including Plaintiff's physician, would have
12 prescribed the Zimmer NexGen Knee, or no consumer, including Plaintiff, would have
13 purchased and/or used the Zimmer NexGen Knee.

14 59. Defendants failed to timely and reasonably provide adequate instructions and
15 training concerning safe and effective use of the Zimmer NexGen Knee. Had they done so,
16 healthcare professionals, including Plaintiff's physician, could have safely and effectively
17 implanted the Zimmer NexGen Knee, without causing serious pain and injury to patients,
18 including Plaintiff.

19 60. The Zimmer NexGen Knee, which was researched, developed, designed, tested,
20 manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released
21 into the stream of commerce by Defendants, was defective due to inadequate post-marketing
22 warnings and/or instruction because, after Defendants knew or should have known that there was
23 reasonable evidence of an association between the Zimmer NexGen Knee and knee replacement
24 loosening causing serious injury and pain. Defendants failed to provide adequate warnings to
25 health care professionals and the consuming public, including Plaintiff, and continued to
26 aggressively promote the Zimmer NexGen Knee.

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61. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

62. As a direct and proximate result of the conduct of Defendants as aforesaid, Plaintiff suffered serious and permanent non-economic and economic injuries.

63. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III

(Products Liability – Defective Design)

64. Plaintiff repeats and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

65. Defendants is the researcher, developer, manufacturer, distributor, marketer, promoter, supplier and seller of the Zimmer NexGen Knee, which is defective an unreasonably dangerous to consumers.

66. The Zimmer NexGen Knee is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. The Zimmer NexGen Knee is defective in design or formulation in that it lacks efficacy and/or it poses a greater likelihood of injury than other knee replacement devices and similar knee replacement devices on the market and is more dangerous than ordinary consumers can reasonably foresee.

67. If the design defect were known at the time of manufacture, a reasonable person would have concluded that the utility of the Zimmer NexGen Knee did not outweigh the risk of marketing a product designed in that manner.

68. The defective condition of the Zimmer NexGen Knee rendered it unreasonably dangerous and/or not reasonably safe, and the Zimmer NexGen Knee was in this defective condition at the time it left the hands of the Defendants. The Zimmer NexGen Knee was expected to and did reach consumers, including Plaintiff Kim Sizemore, without substantial

1 change in the condition in which it was designed, manufactured, labeled, sold, distributed,
2 marketed, promoted, supplied and otherwise released into the stream of commerce.

3 69. Plaintiff and her physician were unaware of the significant hazards and defects in
4 the Zimmer NexGen Knee.

5 70. The Zimmer NexGen Knee was unreasonably dangerous and/or not reasonably
6 safe in that it was more dangerous than would be reasonably contemplated by the ordinary user.
7 During the period that Plaintiff used the Zimmer NexGen Knee, it was being utilized in a manner
8 that was intended by Defendants.

9 71. At the time Plaintiff received and used the Zimmer NexGen Knee, it was
10 represented to be safe and free from latent defects.

11 72. Defendants is strictly liable to Plaintiff for designing, manufacturing, and placing
12 into the stream of commerce a product which was unreasonably dangerous for its reasonably
13 foreseeable uses at the time it left the control of Defendants because of the design defects.

14 73. Defendants knew or should have known of the danger associated with the use of
15 the Zimmer NexGen Knee, as well as the defective nature of the Zimmer NexGen Knee, but has
16 continued to design, manufacture, sell, distribute, market, promote and/or supply the Zimmer
17 NexGen Knee so as to maximize sales and profits at the expense of the public health and safety,
18 in conscious disregard of the foreseeable harm caused by the Zimmer NexGen Knee.

19 74. As a direct and proximate cause of the design defect and Defendants' misconduct
20 as set forth herein, Plaintiff has suffered and continues to suffer serious and permanent non-
21 economic and economic injuries.

22 75. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory
23 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other
24 relief as the Court deems proper.

25 **COUNT IV**

26 **(Negligence)**

27 76. Plaintiff incorporates by reference each and every paragraph of this Complaint as
28 if fully set forth herein and further alleges as follows:

1 77. At all relevant times, Defendants had a duty to exercise reasonable care in the
2 design, formulation, testing, manufacture, marketing, sale, and distribution of Zimmer NexGen
3 Knee, including a duty to ensure that Zimmer NexGen Knee did not pose a significantly
4 increased risk of bodily injury to its users.

5 78. Defendants had a duty to exercise reasonable care in the advertising and sale of
6 Zimmer NexGen Knee, including a duty to warn Plaintiff and other consumers, of the dangers
7 associated with the consumption of Zimmer NexGen Knee that were known or should have been
8 known to Defendants at the time of the sale of Zimmer NexGen Knee to the Plaintiff.

9 79. Defendants failed to exercise reasonable care in the design, testing, manufacture,
10 marketing, sale and distribution of Zimmer NexGen Knee because Defendants knew or should
11 have known that Zimmer NexGen Knee had a propensity to cause serious injury, including
12 loosening and revision surgery

13 80. Defendants failed to exercise ordinary care in the labeling of Zimmer NexGen
14 Knee and failed to issue adequate pre-marketing or post-marketing warnings to prescribing
15 doctors and the general public regarding the risk of serious injury, including, loosening and
16 revision surgery.

17 81. Defendants knew or should have known that Plaintiff could foreseeably suffer
18 injury as a result of Defendants' failure to exercise ordinary care as described above.

19 82. Defendants breached their duty of reasonable care to Plaintiff by failing to
20 exercise due care under the circumstances.

21 83. As a direct and proximate result of Defendants' acts and omissions, including
22 their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and
23 distribution of Zimmer NexGen Knee, Plaintiff was implanted with Zimmer NexGen Knee and
24 suffered severe and debilitating injuries, economic loss, and other damages, including but not
25 limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of
26 balance, immobility, and pain and suffering, for which they are entitled to compensatory and
27 equitable damages and declaratory relief in an amount to be proven at trial.

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1 limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of
2 balance, immobility, and pain and suffering, for which they are entitled to compensatory and
3 equitable damages and declaratory relief in an amount to be proven at trial.

4 100. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory
5 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other
6 relief as the Court deems proper.

7 **COUNT VII**

8 **(Punitive Damages)**

9 101. Plaintiff repeats and incorporate by reference all other paragraphs of this
10 Complaint as if fully set forth herein.

11 102. Plaintiff is entitled to punitive damages because the Defendants' wrongful acts
12 and/or omissions were wanton or in conscious disregard of the rights of others.

13 103. The Defendants misled both the medical community and the public at large,
14 including Plaintiff herein, by making false representations about the safety and efficacy of the
15 Zimmer NexGen Knee and by failing to provide adequate instructions and training concerning its
16 use. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and
17 permanent side effects and risks associated with the use of the Zimmer NexGen Knee despite
18 available information demonstrating that the Zimmer NexGen Knee could loosen and separate,
19 causing serious harm to patients.

20 104. Such risks and adverse effects could easily have been avoided had Defendants not
21 concealed knowledge of the serious and permanent side effects and risks associated with the use
22 of the Zimmer NexGen Knee or provided proper training and instruction to physicians regarding
23 use of the Zimmer NexGen Knee.

24 105. Defendants' misrepresentations included knowingly withholding material
25 information from the FDA, the medical community and the public, including Plaintiff,
26 concerning the safety of the Zimmer NexGen Knee.

27 106. Defendants were or should have been in possession of evidence demonstrating
28 that the Zimmer NexGen Knee caused serious side effects. Nevertheless, Defendants continued

1 to market the Zimmer NexGen Knee by providing false and misleading information with regard
2 to its safety and efficacy.

3 107. Defendants failed to provide warnings that would have dissuaded health care
4 professionals from using the Zimmer NexGen Knee, thus preventing health care professionals
5 and consumers, including Plaintiff, from weighing the true risks against the benefits of using the
6 Zimmer NexGen Knee.

7 108. Defendants failed to provide adequate training and instructions to physicians that
8 could have prevented failure of the Zimmer NexGen Knee causing serious harm and suffering to
9 patients, including Plaintiff Kim Sizemore.

10 WHEREFORE, Plaintiff demands judgment against Defendants for compensatory
11 damages and punitive damages, together with interest, costs of suit and attorneys' fees and such
12 other relief as the Court deems proper.

13 WHEREFORE, Plaintiff prays for relief against Defendants, jointly and severally, as
14 follows:

15 1. Compensatory damages, in excess of the amount required for federal diversity
16 jurisdiction, and in an amount to fully compensate Plaintiff for all her injuries and damages, both
17 past and present;

18 2. Special damages, in excess of the amount required for federal diversity
19 jurisdiction and in an amount to fully compensate Plaintiff for all of her injuries and damages,
20 both past and present, including but not limited to, past and future medical expenses, costs for
21 past and future rehabilitation and/or home health care, lost income, permanent disability,
22 including permanent instability and loss of balance, and pain and suffering.

23 3. Double or triple damages as allowed by law;

24 4. Attorneys' fees, expenses, and costs of this action;

25 5. Pre-judgment and post-judgment interest in the maximum amount allowed by
26 law; and

27 6. Such further relief as this Court deems necessary, just, and proper.

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JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

DATED this 12th day of November, 2010.

MARQUIS & AURBACH

By /s/ Joshua L. Benson
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and

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